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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,452	01/27/2000	Takaaki Inoue	4406-0012-2	9887

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1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

WACHTEL, ALEXIS A

ART UNIT	PAPER NUMBER
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1764

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/492,452

Applicant(s)

INOUE

Examiner

Alexis Wachtel

Art Unit

1764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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***Detailed Action***

***Response to Amendment***

1. Applicant's amendment and accompanying Remarks filed 10-8-2003 have been entered and carefully considered.

The amendment is sufficient to overcome the anticipation and obviousness rejections of claims 1-17 since Applicant's arguments have shown that the relied on prior art does not fairly disclose the claimed invention. However, an updated search yielded new prior art that provides a new basis of rejection as shown below. Applicant's arguments are rendered moot in view of the new grounds of rejection.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claims 5 and 6, it is not clear how a time calculator can calculate a presumed execution time while the synthesizing process is carried out. A "presumed execution" time is calculated before a process rather than during a process as the Applicant claims. Perhaps Applicant intended to communicate the "execution time is calculated in real time". Clarification is required. As they stand, claims 5 and 6 are so incomprehensible as to preclude examination on the merits.

***Claim Rejections - 35 USC § 102***

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-4, 7, 8-17, are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,282,149 to Grandone et al.

Grandone et al disclose a biological sample analyzer, wherein instrument systems used to perform an assay of each of the biological samples loaded into the analyzer are operated in accordance with a schedule developed by a scheduler program. The scheduler program determines a time allowance for performing operations by instrument systems for conducting an assay on each biological sample from a load list indicating the type of assay to be conducted on each biological sample. The time allowance determined is adapted to accommodate variations in actual performance of system operations on each sample so that the assays of the biological samples can be carried out in accordance with a reliable and reproducible schedule (Col 6, lines 19-34). Examiner notes that the time allowance is effectively pre-calculated and constitutes a presumed process execution time. In particular, the scheduler program allows for scheduling the tasks performed by the analyzer in order to assure that certain tasks are performed within allowable time frames and with favorable throughput. Stage 1 includes procedures for creating a list of time blocks, a block descriptor for each time block, estimating the running time for each block and sorting the load list. Stage 2 includes procedures that establish the schedule of time

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blocks for each specimen sample so that the operations of a time block of a sample being scheduled do not conflict with any time blocks that have already been scheduled and that incubation limits between time blocks are not exceeded (Col 10, lines 27-44). The time blocks represent one or more operations or activities to be performed by the analyzer systems upon or for that sample. Each specimen sample typically has associated with it several time blocks. For example, Sample 1 (as well as Sample 2 and 3) has three time blocks associated with it, Sample 4 has four time blocks associated with it (Col 11, lines 1-8). Examiner notes that an individual time block constitutes a partial time allowance for a particular assay. Since the time blocks are scheduled, the scheduling software is inherently capable of adding up the times associated with each time block in order to obtain a workable process schedule.

The operator-user enters a load list via an input panel (54) with menu prompts on a display (55) (Col 9, lines 32-34). The display is capable of showing presumed process execution times in graphical form.

The biological sample analyzer includes a fluid moving system 16 that transfers fluid from reagent bottles to separation wells and from well to well (Col 8, lines 51-53). The fluid moving system constitutes a liquid dispenser. The fluid moving system includes a pipette/probe assembly that includes syringes (e.g. a 250ul sample syringe and 2500ul diluent syringe) (Col 8, lines 44-47). Examiner notes that the 2500ul diluent syringe implies the use of a diluting solvent. Additionally, the Examiner notes that the fluid moving system has its own time blocks for the various actions that it performs. The fluid moving system is also interpreted as a stirring system since injection or withdrawal

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of a fluid by the fluid moving system introduces agitation to a target vessel into which fluid is placed.

The biological sample analyzer also includes a heating system to warm reagents and reaction cells to appropriate operating temperatures (Col 10, lines 21-23). Examiner notes that it is reasonable to assume that the heating system operates under the control of a CPU and or controller per Fig.1. Without such control means it would not be possible to warm reaction cells and reagents to appropriate operating temperatures. Examiner additionally notes that Data Storage (36) is provided for the biological sample analyzer and is capable of being configured to memorize ramp-up and ramp-down temperature sensor data.


In additional embodiments, the biological analyzer can take into account sample position, reagent pack location and instrument parameters (Col 13, lines 32-34).

### **Conclusion**

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alex Wachtel, whose number is (703)-306-0320. The Examiner can normally be reached Mondays-Fridays from 10:30am to 6:30pm.

If attempts to reach the Examiner by telephone are unsuccessful and the matter is urgent, the Examiner's supervisor, Mr. Glenn Caldarola can be reached at (703) 308-6824. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Glenn Caldarola  
Supervisory Patent Examiner  
Technology Center 1700